

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(SOUTHERN DIVISION)**

EXEGI PHARMA, LLC,

*

Plaintiff

*

v.

*

Case No.: 19-cv-2479-LKG

VSL PHARMACEUTICALS, INC.

*

Defendant.

MEMORANDUM OPINION

This case is the latest round in a long running corporate dispute regarding several strains of probiotics. Pending before the Court is Defendant VSL Pharmaceuticals, Inc.’s Motion to Compel Production related to its counterclaims against and defenses to Plaintiff ExeGi Pharma, LLC and Third-Party Defendant Professor Claudio De Simone (hereinafter “the De Simone Parties”). ECF No. 65-1. Several points of disagreement between the parties are common to many discovery disputes. VSL has issued broad discovery requests, which, if responded to literally, would impose burdens on the De Simone Parties beyond what the Federal Rules of Civil Procedure contemplate. The De Simone Parties, in turn, have provided some discovery – albeit belatedly – but have largely objected to the requests, allegedly refusing to provide most discovery until VSL narrows its requests. Additionally, there are also multiple substantive disputes between the parties as to the proper scope of discovery. This Opinion will resolve those disputes, as well as provide the parties a path forward to properly address both the breadth of VSL’s requests and the legitimate need for the De Simone Parties to provide more complete responses. For the reasons discussed below, as well as those noted by the Court during the January 4, 2023 hearing, ECF Nos. 68, 71, VSL’s Motion to Compel will be granted, in part, and denied, in part, without prejudice.

BACKGROUND

On August 27, 2019, ExeGi Pharma, LLC, a Maryland-based corporation that develops probiotic medicines, filed suit against VSL Pharmaceuticals, Inc., a Virginia-based corporation that also works with probiotics. ECF No. 1, at 9. This is not the first time that the parties have been involved in litigation against each other, nor the first time that the parties have been involved in litigation over related issues before this Court.

The history of the dispute is set forth in this Court’s Opinion in *DeSimone v. VSL Pharmaceuticals, Inc.*, 133 F.Supp.3d 776 (D. Md. 2015):

Claudio De Simone, a Professor of Gastroenterology and Immunology who has done extensive research in the field of probiotics, and two fellow researchers were granted United States Patent number 5,716,615 (the “615 Patent”) for “Dietary and Pharmaceutical Compositions Containing Lyophilized Lactic Bacteria, Their Preparation and Use” . . . The 615 Patent was one of a number of patents De Simone secured based on his probiotic research. The 615 Patent consisted of a pharmaceutical combination of eight strains of pure lactic acid bacteria that can be used as treatment for a number of medical conditions, including various gastrointestinal disorders and hypercholesteremia, and was the basis for the probiotic now sold as VSL# 3. To produce the specific VSL# 3 product under the 615 Patent, De Simone also developed certain “know-how,” a type of trade secret which in this instance consists of a unique biochemical profile, formulae, processes, data, and other technical and non-technical information necessary to make, develop, and use VSL# 3.

Id. at 780. In 2000, Professor De Simone and his business partners entered into a business agreement to bring the various products he had patented to the United States as nutritional supplements. *Id.* at 781. To facilitate this, the three of them incorporated VSL as a new corporation in Delaware. *Id.*

Over time, according to the De Simone Parties, VSL#3 became the “gold standard” for probiotics. *Id.* at 783. Professor De Simone asserted that the success of the product strained the relationship between him and his business partners. *Id.* Specifically, Professor De Simone’s

business partners desired to increase their profit margins by using cheaper ingredients to make VSL#3. *Id.* Professor DeSimone, however, rejected this proposal. *Id.* What emerged thereafter was nearly a decade of contracts and contractual disputes over the ownership of VSL#3. *Id.* at 783-85. “By mid–2014, the working relationship between De Simone and [his business partners] had completely broken down.” *Id.* at 785. As of February 2015, VSL continued to distribute VSL#3 in the United States but had stopped paying Professor De Simone any royalties from those sales. *Id.* at 786.

In October 2014, a marketer of VSL#3 and trusted associate of Professor De Simone founded a competing corporation, ExeGi Pharma, aimed at bringing a competing version of VSL#3 to market. *Id.* at 787. Soon thereafter, ExeGi Pharma announced that it would be launching a generic version of VSL#3 supported by Professor De Simone’s “Know How.” *Id.* The generic version would be called “Visbiome.” *Id.*

In May 2015, Professor De Simone filed suit in this Court seeking, among other things, a declaratory judgment that he owned the “Know How” used to formulate and produce VSL#3. No. TDC-15-1356, ECF No. 1. On October 9, 2018, the Court directly addressed the issue of the ownership of the “Know How” in deciding the parties’ cross-motions for summary judgment. No. TDC-15-1356, ECF No. 676. Relying on, among other things, one of the agreements at issue, the Court determined that Professor De Simone owned the “Know How.” *See id.* at 12-13. (“Regardless of what the parties believed the term ‘VSL#3’ to mean, if Mendes did not own the Know-How at the time of the Mendes Agreement, there is no way to read it as having transferred the Know-How to VSL. . . . The Court, thus, concludes as a matter of contract interpretation, DeSimone owns the Know-How.”).

In November 2018, a jury of this Court returned a verdict in favor of Professor De Simone and ExeGi Pharma on all counts against VSL and two affiliated corporations, finding them liable for false advertising of VSL#3 in violation of the Lanham Act, 15 U.S.C. § 1125(a). No. TDC-15-1356, ECF No. 824, at 3. In light of that verdict and pursuant to a Motion filed by the De Simone Parties, on June 20, 2019, the Court issued the Permanent Injunction, which enjoined the VSL Parties from:

- 1) stating or suggesting in VSL#3 promotional materials directed at or readily accessible to United States consumers that the present version of VSL#3 produced in Italy (“Italian VSL#3”) continues to contain the same formulation found in versions of VSL#3 produced before January 31, 2016 (“the De Simone Formulation”), including but not limited to making statements that VSL#3 contains the “original proprietary blend” or the “same mix in the same proportions” as earlier versions of VSL#3; and
- 2) citing to or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL #3 as relevant or applicable to Italian VSL#3.

No. TDC-15-1356, ECF No. 930, at 2. In *De Simone v. Alfasigma USA, Inc.*, 847 F. App’x 174 (4th Cir. 2021), the United States Court of Appeals for the Fourth Circuit affirmed the jury verdict, and the first provision of the permanent injunction, while vacating the second provision. *Id.* at 184.

Just two months after the entry of the permanent injunction in the first case, ExeGi Pharma filed a second lawsuit in this Court, out of which arises the current discovery dispute. ECF No. 1. In its Complaint, ExeGi Pharma alleges that “VSL Inc. and Alfasigma chose not to remove or revise VSL#3’s false advertising and continued trying to sell VSL#3 with the same materially false claims that served as the basis for the jury’s decision.” *Id.* at 7. According to ExeGi Pharma, such efforts were, however, unsuccessful since sales of VSL#3 supposedly cratered in favor of Visbiome. *Id.* at 7-8.

VSL allegedly responded to its sales losses by mailing letters to ExeGi Pharma's subcontractors responsible for producing Visbiome informing them that they could not provide the product for ExeGi Pharma until VSL had received confirmation that ExeGi Pharma, in marketing Visbiome, would not reference codes assigned to the physical isolates of the strains in dispute between the parties in the first case before this Court. *Id.* at 8. VSL based this assertion on a ruling it had received from the Court of Rome in July 2019. *Id.* ExeGi Pharma, meanwhile, asserted that these codes – the DSM Codes – were public knowledge that were frequently referenced by companies and researchers separate and apart from the parties involved in the litigation before this Court. *Id.* at 14.

ExeGi Pharma, as a result, in their first count, sought declaratory relief that it has the right to “use and reference the DSM codes in marketing, distributing, and selling Visbiome, and further declaring that ExeGi’s references to the DSM Codes do not constitute false advertising or unfair competition under the Lanham Act.” *Id.* at 9; *see also id.* at 32. ExeGi Pharma, in their second count, also alleged that VSL’s communications tortiously interfered with ExeGi Pharma’s business relationships with its contractors, namely Danisco, Inc. – a Danish corporation that produces bioproducts. *Id.* at 33-36. In their third count, ExeGi Pharma also advanced a claim for common law unfair competition, largely arising out of the same facts supporting their claim for tortious interference with business relationships. *Id.* at 36-38. As relief, ExeGi Pharma sought, among other things, a permanent injunction barring VSL from continuing to make such communications. *Id.* at 38.

In response, VSL filed its own counterclaim against ExeGi Pharma, as well as a Third-Party Complaint against Professor De Simone. ECF No. 5. VSL asserted that Professor De Simone’s assertion that he invented the probiotic formulation that would become VSL#3 was false.

Id. at 5. VSL emphasized that while serving as President and CEO of VSL from 2000 to 2014, Professor De Simone directed the organization to spend millions of dollars on clinical trials of VSL#3. *Id.* at 6. VSL further asserted that it maintained the trademark for VSL#3, and that once production of VSL#3 had transferred to the United States, the makeup of VSL#3 had changed significantly from its original formulation. *Id.* at 4, 7. VSL also asserted that, in its packaging, ExeGi Pharma had illegally made reference to the DSM codes, improperly suggesting that ExeGi Pharma and Professor De Simone owned the accounts. *Id.* at 12. As they allegedly did in their letter to at least one of ExeGi Pharma's contractors, VSL emphasized a ruling from the Court of Rome that VSL owned the accounts. *Id.*

VSL also provided its own interpretation of the happenings in and results of the first case in the U.S District Court for the District of Maryland. *See id.* at 13-18. VSL asserted that ExeGi Pharma misrepresented the jury's conclusions in the first case. *Id.* at 18-19. Specifically, VSL asserted that ExeGi Pharma falsely claimed after the first case that the jury found that all of the contested advertisements discussed in the first case violated the Lanham Act. *Id.* at 18. VSL further asserted that ExeGi Pharma falsely claimed that the jury had determined that VSL#3 "was an inferior, unsafe, less effective, and unproven product." *Id.* VSL also claimed that, among other things, ExeGi Pharma falsely asserted that:

- The jury found that CSL-manufactured VSL#3 contains seven, not eight, strains of bacteria;
- The jury found that there were no clinical studies or published articles that supported the safety and efficacy of CSL-manufactured VSL#3; and
- The jury found CSL-manufactured VSL#3 to be a "counterfeit" or "knock off" product.

VSL further alleged that De Simone and ExeGi Pharma engaged in false and misleading marketing, representing that:

- CSL-manufactured VSL#3 contains seven, not eight, strains of bacteria;
- No clinical studies or published articles exist that support the safety and efficacy of CSL-manufactured VSL#3;
- CSL-manufactured VSL#3 is a “counterfeit” or “knock off” product;
- De Simone “invented” the probiotic formulation that came to be known as VSL#3;
- CSL-manufactured VSL#3 contains a different probiotic formulation that uses different bacterial ingredients than VSL#3 previously manufactured by Rhodia/DuPont/Danisco;
- Visbiome has been the subject of over 70 human clinical trials;
- Visbiome “has been the subject of over 70 human clinical trials as medical food in the dietary management of gastrointestinal and liver disorders;” and,
- CSL-manufactured VSL #3 has been “discontinued” or “recalled”.

Id. at 19. According to VSL, each of these statements was “false and misleading. *Id.* As a result, VSL claimed that the De Simone Parties had engaged in false advertising in violation of the Lanham Act. *Id.* at 26. VSL further asserted that the De Simone Parties had not limited their false statements to advertisements, but had sent letters to VSL’s distributors and retailers and to clinicians and universities planning to study VSL#3, thus committing the tort of unfair competition. *Id.* at 28. According to VSL, the letters that the De Simone Parties sent also tortuously interfered with VSL’s business relationships with its, and one of its partner’s distributors and retailers. *Id.* at 28-30. Finally, VSL alleged that each of the false statements and letters referenced constituted a tort for injurious falsehood. *Id.* at 31-32. As relief, VSL sought

compensatory damages, as well as injunctive relief barring the De Simone Parties from making the statements identified above, from threatening third parties who “sell, distribute, promote, recommend, publish or engage in clinical studies using CSL-made VSL#3,” and prohibit the De Simone Parties from referencing the DSM Codes in any promotional or commercial materials related to Visbiome. *Id.* at 33-34.

This was not the only case in which VSL was pursuing such claims. Alfasigma, Inc., a corporation associated with VSL responsible for distributing VSL#3, *id.* at 28, filed suit in Circuit Court in Montgomery County, alleging various state torts on the theory that the cease-and-desist letters that the De Simone Parties sent constitute tortious interference, injurious falsehood, libel and unfair competition. ECF No. 41, at 55-56. The state court allegations “included claims based on the fact that the letters were disclosed to the public and that there was at least one false commercial advertising.” *Id.* at 56. In August 2020, the state court granted summary judgment to ExeGi Pharma on all of these claims. *Id.* The Maryland Court of Special Appeals subsequently affirmed the decision. ECF No. 37-1, at 2.

On July 2, 2020, the De Simone Parties moved to dismiss VSL’s counterclaims and its Third-Party Complaint in their entirety. ECF No. 14, at 1. VSL argued, among other things, that VSL was precluded from relitigating issues that it litigated or could have litigated in the first case. *Id.* at 13. Specifically, the De Simone Parties argued that these common issues included the lack of similarity between the De Simone Formulation of VSL#3 and Italian VSL#3, the ownership of the deposited isolates and the corresponding codes, the clinical studies conducted on the De Simone formulation, and whether Professor De Simone invented the VSL#3 formulation. *Id.* at 14-22. On July 23, 2020, VSL amended its counterclaim, adding additional facts, as well as eliminating its claim for unfair competition. ECF No. 16. On September 23, 2020, the De Simone

Parties refiled their Motion to Dismiss again raising the res judicata arguments advanced in their first Motion. ECF No. 22.

On August 17, 2021, the Court granted, in part, and denied, in part, the De Simone Parties' Motion to Dismiss. ECF No. 40. Specifically, the Court found that all claims arising out of the following statements were barred:

- ExeGi's statement "that De Simone 'invented' the probiotic formula that came to be known as VSL#3";
- ExeGi's statement "that CSL-made VSL#3 contains a different probiotic formulation that uses different bacterial ingredients than VSL#3 previously manufactured by Rhodia/DuPont/ Danisco[:]"
- ExeGi's statement "that [Visbiome] has been the subject of over 70 human clinical trials."
- ExeGi's statement "that [Visbiome] has been the subject of over 70 human clinical trials as medical food in the dietary management of gastrointestinal and liver disorders."

Id. at 1-2. Additionally, the Court concluded that any counterclaim "alleging that references in the Visbiome packaging materials to the DSMZ accounts or isolates constitute false advertising, tortious interference, or injurious falsehood by virtue of the alleged fact that De Simone does not own the DSMZ isolates and thus has no legal right to cite or refer to the DSMZ accounts or corresponding DSM codes in Visbiome packaging and package inserts" would also be dismissed with prejudice. *Id.* at 2. At the end of the day, what this left was VSL's counterclaim for false advertising as to the statements set forth in paragraphs 72(a)-(c), 73(a)-(c) and (h)-(j) of the

Amended Counterclaim. ECF No. 41, at 59-60. These statements included alleged assertions by the De Simone Parties that:

- The jury found that CSL-manufactured VSL#3 contains seven, not eight, strains of bacteria;
- The jury found that there were no clinical studies or published articles that supported the safety and efficacy of CSL-manufactured VSL#3;
- The jury found CSL-manufactured VSL#3 to be a “counterfeit” or “knock off” product;
- CSL-manufactured VSL#3 contains seven, not eight, strains of bacteria;
- No clinical studies or published articles exist that support the safety and efficacy of CSL-manufactured VSL#3;
- CSL-manufactured VSL#3 is a “counterfeit” or “knock off” product;
- CSL-manufactured VSL#3 has been “discontinued” or “recalled”;
- ExeGi is the rightful owner of the DSMZ strain bank accounts containing the bacterial strains contained in Visbiome; and
- The eight DSM accounts prominently referenced on the Visbiome packaging and package inserts contain the bacterial strains in the Visbiome product when, in fact, five of those DSM accounts contain entirely different bacteria.

ECF No. 16, at 20-21. However, the Court determined that even regarding such, any claims regarding statements made on or before April 16, 2019 – the date of Alfasigma’s Complaint in Montgomery County Circuit Court – were likewise barred. ECF No. 41, at 56-57.

On December 13, 2021, VSL issued its first set of Interrogatories and Requests for Production on the De Simone Parties. ECF No. 65-3, at 60, 69. On March 3, 2022, the De Simone Parties provided their responses to VSL’s first set of discovery requests. ECF No. 65-2, at 24, 57.

The De Simone Parties objected on multiple grounds but focused on the breadth of the requests. *See e.g.* ECF No. 65-2, at 58 (“De Simone objects to this Request on the grounds that it is massively overbroad, unduly burdensome and disproportionate to the needs of the case.”). Over the course of the next two months, the parties exchanged several communications related to the appropriateness of VSL’s requests, as well as whether the De Simone Parties’ objections were sufficiently particular and well-placed. ECF No. 65-3 at 235-343. Additionally, the De Simone Parties provided amended responses. *See id.* at 44.

On October 4, 2022, VSL filed the pending Motion to Compel, complete with attachments, which included the De Simone Parties’ Opposition, as well as VSL’s Reply in Support. ECF No. 65. On January 4, 2022, the Court held a hearing on the pending Motion. ECF No. 68, 71.

LEGAL STANDARD

Federal Rule of Civil Procedure 37(a) “authorizes the basic motion for enforcing discovery obligations.” Charles Alan Wright, et al., 8B Fed. Prac. & Proc. Civ. § 2285 (3d ed. 1998). Where a party fails to answer a request for production of documents or an interrogatory, the Rule allows the opposing party to move for an order compelling an answer. Fed. R. Civ. P. 37(a)(3)(B)(iii)-(iv). The moving party must certify in the motion that it has conferred, or attempted to confer, in good faith with opposing counsel in an effort to obtain the desired material without court involvement. Fed. R. Civ. P. 37(a)(1). District courts enjoy substantial discretion in managing discovery, including granting or denying motions to compel. *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc.*, 43 F.3d 922, 929 (4th Cir. 1995).

ANALYSIS

As discussed during oral argument on the pending Motion, the current dispute arises out of four common issues: 1) whether VSL is entitled to discovery of materials from April 16, 2019 and

before; 2) whether VSL is entitled to any discovery related to ownership of the DSM accounts; 3) the breadth of Plaintiff's requests – specifically whether the information requested is relevant to each party's remaining claims and whether responding to the requests as written would impose an undue burden on the De Simone Parties; and 4) whether the De Simone Parties' objections to VSL's requests are proper and stated with sufficient particularity. ECF No. 71, at 3-5.

In addressing these questions, three considerations are important. First, the Court must review the requests under the relevancy and proportionality standards set forth in Federal Rule of Civil Procedure 26(b). *Crete Carrier Corp. v. Sullivan & Sons, Inc.*, No. ELH-21-0328, 2022 WL 1203652, at *13 (D. Md. Apr. 21, 2022). Pursuant to Fed. R. Civ. P. 26(b)(1):

Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Second, VSL's sole remaining claim is a claim for false advertising under the Lanham Act.

To prevail on a claim for false advertising under the Lanham Act, a plaintiff must establish that:

- (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product;
- (2) the misrepresentation is material, in that it is likely to influence the purchasing decision;
- (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience;
- (4) the defendant placed the false or misleading statement in interstate commerce; and
- (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002). The contested statement may either be “false on its face” or “although literally true, likely to mislead and to confuse consumers given the merchandising context.” *Id.* at 273 (quoting *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 434 (4th Cir. 1997)). If an advertisement is literally false, a party can succeed on a false advertising claim without evidence of any consumer deception. *Id.* However, if “a plaintiff’s theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers.” *Id.* (quoting *Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992)). When a false advertising claim involves multiple statements, a plaintiff “may not mix and match statements, with some satisfying one Lanham Act element and some satisfying others”; rather, one challenged statement must satisfy all five elements. *Verisign, Inc. v. XYZ.COM, LLC*, 848 F.3d 292, 299 (4th Cir. 2017).

Further, as noted above, this claim is limited to the statements which the Court identified in its ruling denying, in part, the De Simone Parties’ Motion to Dismiss. Accordingly, to the extent that the parties’ positions on the pending Motion seeks to relitigate whether certain statements are subject to *res judicata*, the Court is bound by its prior rulings denying, in part, the De Simone Parties’ Motion to Dismiss. To the extent that the De Simone Parties intend to argue that although the statements are actionable, discovery related to them was already produced in the previous litigation, the De Simone Parties must justify such assertions with specific information regarding what relevant information was previously produced.

With these considerations in mind, the Court addresses the significant disputes between the parties below.¹

I. The Timeframe Applicable to VSL's Requests.

As the De Simone Parties highlight, ECF No. 65-3, at 28, VSL's original interrogatory responses and requests for production failed to include dates regarding how far back several of their requests reached. *Id.* at 60, 69. However, in their Motion to Compel, as well as at the hearing on the dispute, VSL limited their requests to information which originated on or after the date of the jury award in the first case – November 21, 2018.² ECF No. 65-2, at 15; ECF No. 71, at 15-16.

VSL's revised timeframe is appropriate under the facts of the case, and in light of the Court's previous rulings. As VSL explained during the hearing on the pending Motion, although VSL may only seek relief regarding statements that were made after April 16, 2019, relevant information regarding such statements may have arisen on or before that particular date. *See* Fed. R. Civ. P. 26(b)(1) ("Information within this scope of discovery need not be admissible in evidence to be discoverable."). For example, according to VSL, ExeGi Pharma allegedly made statements

¹ Each party has requested costs and fees associated with litigating the pending Motion. ECF No. 65-2, at 2; ECF No. 65-3, at 39. As discussed below, each party has a reasonable basis for its position. *See Hare v. Comcast Cable Communications Management, LLC*, 564 Fed.Appx. 23, 24 (4th Cir. 2014) ("Rule 37(a)(5)(B) provides for an award of expenses if a motion to compel discovery is denied, unless the motion was substantially justified or other circumstances make an award of expenses unjust." (internal quotation marks omitted)). Accordingly, the Court will not grant either party costs or fees. Likewise, the De Simone Parties fault VSL for not attaching its discovery requests to its initial filing. ECF No. 65-3, at 19. However, as both parties highlighted in their letter to the Court, given the need for this Motion to be resolved so that the parties may complete discovery, ECF No. 69, at 2, the Court will decide the substance of the dispute.

² In its Motion to Compel, VSL identified the date of the jury verdict as November 18, 2018. The verdict was entered on November 21, 2018. No. TDC-15-1356, ECF No. 826. Accordingly, the Court shall use that as the proper date for the purposes of limiting VSL's discovery requests.

after April 16, 2019, that VSL had been discontinued and in its place, individuals should purchase ExeGi Pharma's product – Visbiome. ECF No. 71, at 16; *see also* ECF No. 65-3, at 341 (alleging that the Visbiome website states that VSL#3 is no longer for sale at many retailers). To the extent that the De Simone Parties' statements were based on call scripts, communications with ExeGi Pharma's third-party advertisers, or training materials for ExeGi Pharma's employees developed prior to April 16, 2019, these materials are relevant in that they will help identify additional actionable statements that were made based on these materials after April 16, 2019.

The De Simone Parties' arguments, in response, are unpersuasive. The majority of their Opposition focuses on the discovery requests as to which VSL did not initially attach the temporal limitation offered at oral argument. While these arguments are well-taken, as explained above, VSL has since attached the November 2018 date to each of its requests, other than those requesting statements that may themselves be actionable. Furthermore, although the De Simone Parties complain that VSL fails to identify the requests which may be properly limited to April 2019, ECF No. 65-3, at 29, VSL's Motion to Compel makes clear that any request for actionable statements may be limited to communications that occurred on or after that date. ECF No. 65-2, at 14.

Finally, the De Simone Parties argue in their Opposition that VSL's timeframe was improper because the De Simone Parties have not uncovered any statements that they made after April 16, 2019 to which underlying training materials could be tied. ECF No. 65-3, at 30. As an initial matter, the De Simone Parties' argument concerns the relevance of the material requested as a whole, as opposed to the proper time period applicable to the requests. Nonetheless, as VSL highlighted during argument on the pending Motion, in a letter dated June 17, 2022, VSL highlighted several publicly available statements that might be actionable under this Court's prior ruling allowing VSL to pursue a Lanham Act claim related to a limited number of statements. ECF

No. 71, at 27-28. For example, VSL highlighted language on Visbiome’s website stating that “a new imitation formula sold as ‘VSL#3’ has not been the subject of any human clinical trials which have resulted in peer reviewed publications.” ECF No. 65-3, at 340-41. The language in the statement that refers to VSL#3 as an imitation may be actionable given this Court’s prior ruling that VSL could pursue claims arising out of alleged statements by the De Simone Parties that VSL#3 was a counterfeit or a knock-off. The portions of the statement stating that VSL#3 has not been the subject of any human clinical trials might be actionable given the Court’s prior ruling that VSL could pursue Lanham Act claims for statements that “no clinical studies or published articles exist that support the safety and efficacy of CSL-manufactured VSL#3.” ECF No. 41, at 59-60.

Although the De Simone Parties dispute whether statements referring to VSL#3 as counterfeit are actionable, ECF No. 71, at 31, as explained during the hearing, this Court, in denying the De Simone Parties’ Motion to Dismiss, has already determined that they are. Likewise, to the extent that the De Simone Parties argue that the context in which the statements were made means they were not actionable, *id.* at 42, this is an argument more properly suited to a motion for summary judgment. At this stage of the case, the proper question is simply whether VSL is entitled to discovery regarding statements that may be actionable or lead to other statements that are actionable. Given the substantive overlap between the statements identified in VSL’s June 17, 2022 letter and the statements the Court has allowed VSL to proceed on, discovery regarding these statements is appropriate.³

³ Additionally, the De Simone Parties’ argument is undercut by the fact that it focuses largely on the merits of Plaintiff’s Lanham Act claim, as opposed to any burden from producing the discovery requested. Although the De Simone Parties described their argument as relating to proportionality, ECF No. 71, at 32, the De Simone Parties did not explain with any degree of specificity the particular burden they would face from producing discovery related to such statements, or more importantly, from a six-month expansion of the timeframe for discovery.

Accordingly, for the reasons stated above, the timeframe of November 21, 2018 to the present shall be applicable to VSL's discovery requests, except those requests asking for statements that are themselves potentially actionable. The De Simone Parties need not produce any potentially actionable statements that were made on or before April 16, 2019.

II. Discovery Related to the Ownership of the DSM Accounts

The second major area of dispute between the parties concerns multiple discovery requests VSL has issued related to the ownership of the DSM Accounts and the information therein. *See* ECF No. 65-3, at 65 (“Identify and Describe all communications between you and DSMZ regarding the ownership of the DSMZ Accounts.”); *id.* at 77 (requesting documents and communications regarding the DSM codes). ExeGi Pharma objected to these requests on the grounds that “all issues of ownership were already litigated and resolved in the prior litigation.” *Id.* at 99-100. As VSL conceded during the hearing, VSL's current position is that neither party should be entitled to discovery on the issue of ownership of the accounts or the “Know How.” ECF No. 71, at 19-20. However, they may revise their position if the De Simone Parties seek to compel discovery from them regarding issues related to the ownership of the DSM Accounts, the “Know How,” or the bacterial strains at issue. Should the De Simone Parties ultimately seek such discovery, the Court grants VSL leave to re-raise this issue with the Court.

III. The Appropriate Way Forward to Address the Breadth of VSL's Requests and the De Simone Parties' Objections.

The majority of the disputes between VSL and the De Simone Parties concern the breadth of VSL's requests and whether the De Simone Parties have properly responded to them. As discussed during the hearing on the pending Motion, the Court's ability, at the current time, to adequately assess the sufficiency of the De Simone Parties' response is limited, to a degree, by the fact that the De Simone Parties produced additional information shortly before VSL's Reply in

support of the Motion to Compel, and the Court has only limited information regarding the contents of the production. ECF No. 71, at 5; *see also* ECF No. 65-4, at 2 n. 1. Additionally, according to VSL, the De Simone Parties provided additional interrogatory responses shortly before oral argument on the pending Motion. ECF No. 71, at 9. Without additional information regarding precisely what information VSL seeks that the De Simone Parties have not produced, it is difficult for the Court to precisely determine which of the remaining disputes between the parties require resolution at the current time. Nonetheless, the Court will provide the parties a ruling based on its understanding of the matters that remain in dispute, as well as guidance to resolve any remaining disputes not specifically addressed in the parties' filings and during oral argument.

The crux of the dispute arises out of the fact that VSL has issued requests that while commonly employed in litigation by some, if responded to literally, would likely encompass information that would either be irrelevant or unduly burdensome to produce given its limited relevance. *See e.g.* ECF No. 65-3 at 88 (requesting “[d]ocuments and correspondence, including emails and electronic files, between You and the parties to this litigation related to any of the claims, damages, defenses, injuries, or factual allegations set forth in the Complaint or Counterclaim”); *id.* (requesting “[d]ocuments and communications, including any contracts, with Danisco relating to Visbiome”); *id.* at 65 (“Identify all persons who are likely to have personal knowledge of any fact alleged in the pleadings and state the subject matter of the personal knowledge possessed by each person.”). The parties contest the proper means to resolve this dispute. VSL argues that the De Simone Parties, rather than simply objecting, should have attempted to respond to the request, ECF No. 65-4, at 13-14, even if some of the information arguably within the scope of the request would not have been proper for production given the burden to produce it and its limited relevance. For example, all communications between the De

Simone Parties and one of its partners related to Visbiome would not be a proper subject of discovery where Plaintiffs have a single claim limited to these particular types of statements. The De Simone Parties, meanwhile, argue that VSL should have issued narrower requests, ECF No. 65-3, at 6, *id.* at 43, even though that may have meant that VSL inadvertently stopped pursuing certain types of information responsive to its request of which it was not aware. The De Simone Parties additionally note that they have produced some discovery. ECF No. 71, at 38.

Both of the parties' positions have some merit.⁴ A party must have a good faith basis for a discovery request it makes. *R. Ernest Cohn, D.C., D.A.B.C.O. v. Bond*, 953 F.2d 154, 159 (4th Cir. 1991) ("Discovery should not become a 'fishing expedition'."); *Sandcrest Outpatient Servs., P.A. v. Cumberland County Hosp. Sys., Inc.*, 853 F.2d 1139, 1147 (4th Cir. 1988) (noting that the overly broad scope of the request renders it more of a "fishing expedition" and not reasonably calculated to lead to the discovery of admissible evidence); *Jos. A. Bank Clothiers, Inc. v. J.A.B.-Columbia, Inc.*, No. ELH-15-3075, 2017 WL 75746, at *4 (D. Md. Jan. 6, 2017) (Gallagher, M.J.) (discussing the appropriate scope of discovery). Accordingly, it is reasonable for a responding party to seek clarity regarding what might be specific examples of types or categories of information which the requesting party seeks so that it may it not spend needless expense gathering and reviewing documents which might otherwise be of little or no relevance to the case. Conversely, asking a requesting party to proactively narrow its requests to specific, narrowly defined categories of documents creates the risk that a party may inadvertently exclude categories of documents highly relevant to the case of which a party is simply not aware.

⁴ As noted, given the fact that both parties' positions have merit, the Court denies both parties' request for the imposition of fees and costs. However, to the extent that either party ignores the directions of the Court, as detailed in the Opinion, the Court may reconsider either party's request for the fees and costs.

The proper means of addressing this problem requires a case specific inquiry, focused on the specific nature of the case, the stage of the case, the size of the case, the information the parties have already exchanged, and the specific wording of each request at issue. Given the fact that the parties have previously engaged in several rounds of litigation – including one in which the parties engaged in prolonged discovery – and that the subject matter between the two cases was substantially similar – even if not sufficiently so to preclude all of VSL’s counterclaims – as well as the broad nature of several of VSL’s requests, it is reasonable for the De Simone Parties to demand that VSL provide examples of the types or categories of information that it seeks. Importantly, these exemplars should only be that – examples of the types or categories of information that VSL seeks. VSL’s provision of such does not excuse the DeSimone Parties from producing other information that is substantially similar to the examples provided. Nor does it preclude VSL from later requesting other information beyond the examples provided and other types of information that are substantially similar. Once the De Simone Parties have received the examples, they may respond to the requests if they believe that the examples provide sufficient clarity as to the types of information VSL seeks. However, to the extent that the De Simone Parties believe that responding to the requests would still be unduly burdensome – an argument that may be more difficult depending on the degree of specificity and the number of examples – the De Simone Parties may initially provide VSL with only those specific examples and categories of information VSL has provided. The parties may then meet and confer regarding what other categories and types of information are responsive to the request, and the order, based on priority, in which they should be produced.

Importantly, VSL has already provided such examples related to multiple requests. For example, in Interrogatory No. 1, VSL requests the identity of all persons who are likely to have

personal knowledge of any fact alleged in the proceedings. ECF No. 65-3, at 56. Initially, it appears that at least some of the information covered by the request would be unduly burdensome to produce since it concerns facts of which the VSL parties already have knowledge or a responsive individual would have such limited knowledge that naming them would serve to only distract the parties from those individuals most directly relevant to the case. However, the De Simone Parties allegedly have failed to provide any contacts at third party contractors with whom the De Simone Parties allege that VSL allegedly tortiously interfered. *Id.* at 243-44, 267-68. VSL is entitled to such information to test the validity of the De Simone Parties' claims that their relationships with these third parties were harmed, as well as the degree of harm that resulted.

Likewise, as discussed above, VSL has identified several statements responsive to Request for Production No. 11, *id.* at 77, 89, requesting documents or communications referencing or asserting that CSL manufactured VSL#3 is a counterfeit or knock off product. While the De Simone Parties' initial objection that the request as originally phrased is overbroad, VSL's provision of specific examples of statements that were responsive to this request, *id.* at 340, provided sufficient clarity that the De Simone Parties should have been able to begin to respond to the request. Although the De Simone Parties have defended their failure to produce the responsive statement VSL has identified based on slight differences between the phrases in the Amended Complaint and those VSL has identified, as well as the context in which the statements were made, these differences do not justify withholding them in discovery. *See id.* at 47 (arguing that although statements that VSL#3 only contains seven and not eight strains must be produced, the De Simone Parties need not produce a statement that VSL#3 does not have the same strains as the original De Simone Formulation which had eight strains); *see also* ECF No. 71, at 31. To allow such parsing would encourage a level of gamesmanship that would unnecessarily increase

the length and cost of discovery for all parties. The remaining statements in the letter likewise are legitimate examples of statements the De Simone Parties should produce, and produce reasonable discovery related to, including but not limited to scripts in which they are included and training materials instructing staff to use such language. As discussed above, although the Court finds that these statements should be produced, it does not determine, at this time, whether each of these statements, in fact, proves VSL's claim.

While these are only examples of the additional materials that should be provided, the Court is not holding that the De Simone Parties are entitled to "all communications, facts, advertisements, representations, etc." ECF No. 65-2, at 16. Additionally, as noted above, the Court recognizes that the De Simone Parties dispute whether these statements constitute commercial advertisements, and thus are actionable. ECF No. 65-3, at 46-49. Accordingly, in producing such statements, the De Simone Parties may note that they reserve the right to challenge whether such statements are in fact actionable.

A similar approach should be used in responding to VSL's Interrogatories Nos. 17 and 18 to Professor De Simone which, in essence, request facts supporting certain statements the De Simone Parties allegedly made regarding the DSM Codes. *Id.* at 66-67. VSL should either identify at least some of the statements which it believes are the proper subject of litigation, and the De Simone Parties, in response, should identify facts supporting such statements. To the extent that VSL does not have some or all of these statements, the parties may wait to resolve these requests until the De Simone Parties have produced allegedly actionable statements regarding the DSM codes.

There remain several other requests where it is not clear whether VSL has provided sufficient clarity. For example, while the De Simone Parties may not limit their response to

Request for Production No. 9 to only the August 5, 2019 correspondence in the Complaint, VSL is not entitled to all communications with Danisco regarding the DSM codes. *Id.* at 77, 89. The parties should meet and confer on appropriate means to focus production on only those communications targeted to the parties' claims and counterclaims. This approach is equally applicable to VSL's Request for Production No. 13, which broadly requests documents and communications with Pharma Holdings or other resellers relating to the production or distribution of Visbiome, *id.*, ECF No. 65-2, at 19, as well as VSL's Request for Production Nos. 15 and 17 to Professor De Simone and VSL's Request for Production Nos. 15, 17 and 19 to ExeGi Pharma. *Id.* at 20; ECF No. 65-3, at 77-78, 89-90.

Finally, to the extent that the parties have already produced information responsive to a request, they may reference such production with specificity, rather than re-producing information. This may be applicable, for example, to VSL's Request for Production No. 14 to ExeGi Pharma, which seeks representative samples of packaging for Visbiome. ECF No. 65-3, at 77. To the extent that this information has not been produced in the multiple rounds of litigation between the parties, the request is sufficiently concrete that the De Simone Parties are obligated to respond.⁵

The Court directs the parties to use the framework provided above to resolve any remaining disputes. To the extent that the parties are unable to resolve any differences, they may return to the Court, highlighting the specific document requests and interrogatories remaining in dispute, the examples provided by VSL of the types of documents to be produced and responses to be

⁵ Both parties defend their requests, as well as their responses, on the grounds that the other party requested information equally broadly or provided the same insufficient responses of which the other now complains. ECF No. 65-3, at 38, 49-50; ECF No. 71, at 19. As discussed during the hearing, ECF No. 71, at 36-37, the Court decides only the Motion currently pending.

provided, and additional detail regarding the general categories of information that have been provided and which the requesting party believes remain outstanding.

CONCLUSION

For the reasons stated above, VSL's Motion to Compel will be granted, in part, and denied, in part, without prejudice.

Dated: March 3, 2023

/s/
Ajmel A. Quereshi
United States Magistrate Judge